

1043-92

5/14/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Michael G. Sarli
STERIS Corporation
P.O. Box 147
St. Louis, MO 63166-0147

MAY 14 2009

Subject: **LpHse**
EPA Registration No.: 1043-92
Application Date: April 28, 2009
Receipt Date: April 29, 2009

Dear Mr. Sarli:

This acknowledges receipt of the notification identified above submitted under the provision section 3 (c) 9 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10.

Proposed Notification:

- Adding Marketing Claim

Other Comments

Under the First Aid Heading, you must order the rate of exposure from most toxic to least toxic route of exposure and should read as follows:

- If in Eyes
- If on Skin and Clothing
- If Inhaled
- If Swallowed

Based on a review of the material submitted, this notification has been found acceptable:

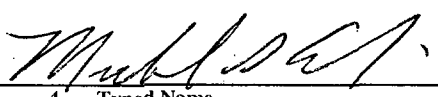
A copy of this notification has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, Stacey Grigsby by telephone at (703) 305-6440

Sincerely,
Stacey Grigsby

CONCURRENCES

SYMBOL				Tracy Lantz		
SURNAME				(Acting) Product Manager (34		
DATE				Regulatory Management Branch II		
				Antimicrobials Division (7510P)		

EPA United States Environmental Protection Agency Washington, DC 20460		Registration Amendment X Other (Notification)	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 1043-92		2. EPA Product Manager	3. Proposed Classification
4. Company/Product (Name) STERIS Corporation/ LpHse		PM # 34	X None Restricted
5. Name and Address of Applicant (include Zip Code) STERIS Corporation P.O. Box 147 St. Louis, MO 63166-0147 Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name	
Section - II			
Explanation: Alternate tagline added This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA			
Section - III			
1. Material This Product will be Packaged In:			
Child-Resistant Packaging Yes* X No	Unit Packaging Yes No X If "Yes" Unit Packaging wgt.	Water Soluble Packaging Yes No X If "Yes" Package wgt	2. Type of Container Metal Plastic X Glass Paper Other (Specify) X - Foil Packet
*Certification must be submitted		No. per container	No. per container
3. Location of Net Contents Information Label X Container		4. Size(s) Retail Container 1/8 fl. oz., 1 fl. oz., 1 qt., 1 gal., 5 gal. And 55 gal.	5. Location of Label Directions On Label X On Labeling accompanying product X
6. Manner in Which Label is Affixed to Product		Lithograph Paper glued X Stenciled	Other
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Michael G. Sarli		Title Lead Regulatory Specialist	Telephone No. (Include Area Code) 314-290-4704
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Lead Regulatory Specialist	
4. Typed Name Michael G. Sarli		5. Date 4/28/09	



April 28, 2009

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
Regulatory Management Branch 1
Antimicrobials Division (7510C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
Attn: PM #34

Re: Notification for LpHse (EPA Reg. No. 1043-92)
Addition of Alternate Tag Line to Label

To Whom It May Concern:

Enclosed in support of the subject action, please find the following:

- Application for Pesticide (EPA Form 8570-1)
- Labeling (1 copy)

The tag line "Serum Effective One Step Germicidal Detergent" has been added as an alternate statement to the previously approved tagline:

If you have any questions I can be reached at 314-290-4704 or at mike_sarli@steris.com.

Sincerely,

Michael G. Sarli
Lead Regulatory Specialist
STERIS Corporation

Enclosures

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LpH[®] se
ONE-STEP GERMICIDAL DETERGENT
(or SERUM EFFECTIVE ONE-STEP GERMICIDAL DETERGENT)

Germicide Fungicide Virucide Tuberculocide
 Deodorizer Cleaner Detergent

When diluted with soft or hard water (400 ppm CaCO₃) even in the presence of organic soil (5% serum)

FOR INDUSTRIAL AND INSTITUTIONAL USE ONLY

Active Ingredients:
 o-phenylphenol.....7.7%
 p-tertiary amylphenol.....7.6%
Inert Ingredients:.....84.7%
Total:100.0%

NOTIFICATION
 Date Reviewed: 3/14/09
 Reviewed By: *[Signature]*

KEEP OUT OF REACH OF CHILDREN
DANGER

See side panel for additional precautionary statements

FIRST AID	
If inhaled	<ul style="list-style-type: none"> •Move person to fresh air. •If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. •Call a poison control center or doctor for further treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> •Take off contaminated clothing. •Rinse skin immediately with plenty of water for 15-20 minutes. •Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none"> •Hold eye open and rinse slowly and gently with water for 15-20 minutes. •Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye. •Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none"> •Call poison control center or doctor immediately for treatment advice. •Have person sip a glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

NET CONTENTS:

STERIS Corporation
 7501 Page Ave.
 St. Louis, Mo 63133 U.S.A.

EPA REG. NO. 1043-92

EPA Est. No. 1043-MO-2

**PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS AND DOMESTIC ANIMALS:**

DANGER: Corrosive. Causes irreversible eye damage. Do not get in eyes, or on clothing. Wear protective eyewear. Wash hands thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARD STATEMENT: (For use on containers 5 gallons and larger) Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

CLEANING AND DISINFECTING WASHABLE, HARD, NON-PORUS SURFACES: To make solution, add one-half fl. oz (15 cc) to each pre-measured gallon of water [or one 1/8 fl. Oz (3.70ml) packet per quart (0.946) of water].and gently mix until solution is uniform. **NOTE:** Always add this product (concentrate) to pre-measured water. Apply solution with a cloth, sponge, mop, brush or by coarse spray using normal cleaning methods. Allow treated surfaces to soak for 10 minutes. Then remove excess solution with a wrung-out applicator. As solution becomes dirty, discard and replace with a fresh one. A properly prepared solution of LpHse intended for use as a hard surface disinfectant has a shelf life of 14 days (use life) when stored in a closed container such as a spray bottle. Before cleaning begins, always sweep or dust mop area to be cleaned thoroughly, removing any gross filth. This is a complete product. Do not add other chemicals. If frozen, thaw and re-mix before use. Use only as directed.

Directions for use with Twin-Neck Dispensing Bottle: To make one gallon (1:256) solution, loosen cap from dispensing chamber. Gently squeeze bottle to fill measuring chamber to the 1/2 fluid ounce line. Remove cap from dispensing chamber. Pour measured product (concentrate) from the chamber into one gallon (128 ounces) of pre-measured cold water and mix well. Apply as directed above.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) and HBV OF SURFACES / OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of a 1:256 use-solution (one-half ounce per 1 gallon) [or one 1/8 fl. Oz (3.70ml) packet per quart (0.946) of water]. Prepare and apply solution as directed in paragraph above.

Contact Time: While the HIV-1 virus is inactivated in 1 minute, use a 10-minute contact time for disinfection of HBV and all organisms on this label.

Infectious Materials Disposal: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious disposal.

CLEANING AND DISINFECTING FOOD PREPARATION, PROCESSING FACILITIES AND EQUIPMENT: Cover or remove all food and packaging materials. Remove all gross soils. Saturate all surfaces with the use-solution (one-half ounce per gallon prepared as directed above). Scrub to loosen all soils. Allow to soak for 10 minutes, then pick up excess solution with a wrung-out applicator. Thoroughly rinse all wetted and cleaned food contact surfaces with potable water.

STORAGE AND DISPOSAL

PROHIBITIONS: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

PESTICIDE DISPOSAL: This germicide, its solutions or rinsings from empty containers, should be disposed of in a toilet or service sink served by a sanitary sewer, or in a landfill approved for pesticides.

CONTAINER DISPOSAL:

(For Packet:) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

(For ≤5 gal:) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

(For > 5 gal.): Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

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GENERAL: Consult Federal, State, and local disposal authorities for approved alternative procedures such as limited open burning.

This non-alkaline phenolic germicidal detergent is a state-of-the-art, concentrated scientifically developed product effective in hard or soft water even in the presence of organic soil (5% blood serum). The use-solution of this product when diluted one-half ounce per gallon of water is specially formulated to clean, disinfect and deodorize in a simple one-step process. With its non-alkaline base, it will remove soap scum and hard water salts which can harbor bacteria. Use this product on washable, hard, non-porous environmental surfaces: floors, walls, counters in food processing preparation and service facilities, veterinary clinics, animal research facilities, healthcare facilities, hospitals, medical and dental offices.

This product is not for use in the neonatal (newborn) units in hospitals specifically isolettes and other infant contact surfaces.

Use for one-step cleaning, disinfecting and deodorizing of stainless or galvanized steel and chrome, glazed porcelain, plastics, glass, glazed tile, washable painted or varnished surfaces, as well as resilient vinyl, linoleum, rubber, glazed terrazzo and glazed concrete floors.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the blood stream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

GERMICIDAL-When tested against *S. aureus* (ATCC 6538), *S. enterica* (ATCC 10708), *P. Aeruginosa* (ATCC 15442), it passes the A.O.A.C. Germicidal Use-Dilution Test when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (one half ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

BROAD SPECTRUM DATA: The following additional organisms pass the A.O.A.C. Use-Dilution Test in 400 ppm A.O.A.C. hard water at a dilution of 1:256 in the presence of 5% organic soil (serum), 10 minutes at 20°C.

Acinetobacter calcoaceticus, ATCC 19606
Candida albicans, Clinical Isolate
Candida parapsilosis, Clinical Isolate
Citrobacter freundii, ATCC 8090
Enterobacter aerogenes, ATCC 13048
Enterobacter cloacae, ATCC 23355
Escherichia coli, ATCC 25922
Klebsiella pneumoniae, ATCC 13883
Proteus mirabilis, Clinical Isolate
Proteus vulgaris, ATCC 13315
Pseudomonas aeruginosa, ATCC 27853

Salmonella typhi, ATCC 6539
Salmonella typhimurium, ATCC 14028
Serratia marcescens, ATCC 8100
Shigella flexneri, ATCC 12022
Shigella sonnei, ATCC 25931
Staphylococcus aureus, ATCC 25923
Staphylococcus aureus, (MRSA), Multiply (Methicillin)-Resistant Clinical Isolate
Staphylococcus epidermidis, ATCC 12228
Streptococcus faecalis, ATCC 19433
Streptococcus pyogenes, ATCC 19615

FUNGICIDAL: When tested against *T. mentagrophytes* (ATCC 9533), it passes the A.O.A.C. Fungicidal Test when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (one-half ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

TUBERCULOCIDAL: When tested against *Mycobacterium tuberculosis var. bovis*, BCG (ATCC 35743), it passes the A.O.A.C. Tuberculocidal Test when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (one-half ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

***VIRUCIDAL:** When tested against Influenza A₂ (Japan) (Clinical Isolate), Herpes simplex Type 2 (ATCC VR 734), Vaccinia (Clinical Isolate) and, Adenovirus Type 2 (ATCC VR 846), it passes the Virucidal Assay (EPA Proposed Method) when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (one-half ounce per 1 gallon) solution in the presence of 5% organic soil (serum), 10 minutes at 20°C.

When tested against Duck Hepatitis B virus (DHBV) as a surrogate for Human Hepatitis B virus (HBV) it passes Virucidal Efficacy Test when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (one-half ounce per 1 gallon) solution in the presence of 5% organic soil (serum), 10 minutes at 24°C.

When tested by an EPA-approved Dilution Method, the HIV-1 (AIDS) virus (Clinical Isolate), with added 5% organic soil (serum), was completely inactivated by a 1:256 (one-half ounce per 1 gallon) solution in 400 ppm A.O.A.C. hard water in 60 seconds at 20°C. Although efficacy at 1 minute contact time has been shown to be adequate against HIV-1, this time would not be sufficient for other organisms. Use a 10-minute contact time for disinfection against all of the organisms claimed.

ODOR CONTROL: It eliminates many odors by killing odor-causing bacteria while simultaneously chemically neutralizing their odors and leaving a pleasant fragrance. Follow "**CLEANING AND DISINFECTING WASHABLE, HARD, NON-POROUS SURFACES**" directions.